

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION**

THE CLEVELAND CLINIC FOUNDATION, et al.,
Plaintiffs,
v.
TRUE HEALTH DIAGNOSTICS LLC,
Defendant.

Civil Action No.
1:17-cv-00198-LMB-IDD

**REPLY IN SUPPORT OF PLAINTIFFS’
MOTION FOR LEAVE TO AMEND COMPLAINT**

Plaintiffs The Cleveland Clinic Foundation (“CCF”) and Cleveland HeartLab, Inc. (“CHL”) (collectively, “Plaintiffs”) moved for leave to amend their complaint to add U.S. Patent No. 9,612,242 (“the ’242 patent”) to this case. (Dkt. Nos. 22-23). The ’242 patent issued on April 4, 2017, just about two weeks ago. The new allegations in the Second Amended Complaint (“SAC”) involve the same infringing conduct and significantly overlap the allegations in the First Amended Complaint (“FAC”) as well as the subject matter of the two patents currently at issue. As soon as the patent issued, Plaintiffs approached Defendant True Health Diagnostics LLC (“True Health”) and attempted to work out an agreement wherein the new patent would be added to the case, a reasonable period would be provided for True Health to evaluate the ’242 patent and respond to the SAC, and any motion practice on the pleadings would be presented to the Court in an orderly and efficient manner for resolution upon a single motion. True Health refused, and its objections are unfounded. Under controlling law, leave to amend should be freely granted, particularly where, as here, nothing has happened yet in the case.

Instead of cooperating with Plaintiffs, True Health refused to try to work out an agreed schedule and demanded that Plaintiffs “guarantee that additional time is built into the schedule” when this Court does not permit parties to set their own deadlines for completion of discovery, the pretrial conference, or for trial. And although Plaintiffs’ counsel tried to work within this Court’s schedule—for example by raising the potentially imminent issuance of the Scheduling Order and trying to work out a mutually-agreeable schedule quickly for True Health to answer before that Scheduling Order issued—True Health now mischaracterizes Plaintiffs’ attempts at hospitable engagement with counsel unfamiliar with this Court’s schedule as seeking “some ulterior tactical advantage.” True Health is wrong, and its accusations have no basis.

In reality, True Health will suffer no prejudice if Plaintiffs motion is granted. This case is in its infancy. Nothing has happened yet. The Scheduling Order has not yet issued. The trial date has not yet been set. Discovery has not yet begun. Having no legitimate basis for opposing Plaintiffs’ motion, True Health ignores controlling law in cases like *Foman* and *Ward Electronics* that hold motions for leave to amend pleadings should be liberally granted, and instead makes unfounded, baseless, and untrue accusations of bad faith and ulterior motives. True Health contends that this Court should deny the motion because, like all patent infringement defendants, it thinks it has a non-infringement defense. Neither of these arguments has any merit.

First, True Health has not offered any evidence to back up its unfounded accusations; nor could it. Plaintiffs are motivated by only one thing—enforcing their patent rights against an infringer who refuses to respect those rights. Before True Health acquired Health Diagnostics Laboratory’s (“HDL”) assets, HDL was an authorized, licensed user of Plaintiffs’ patented technology. True Health’s rejection of the contract between CHL and HDL was not a simple

business decision “to beg[i]n purchasing its MPO testing kits from a different supplier,” but, rather, it was a conscious decision to infringe Plaintiffs’ presumptively valid patent rights. (Dkt. No. 30 at 3.) Because Plaintiffs were and continue to be irreparably harmed by True Health’s illegal conduct, Plaintiffs took immediate action to enforce their patent rights. There is nothing untoward about Plaintiffs’ decision to enforce its patent rights and to assert new patents that issued after the original filing of the complaint.

Second, True Health’s attempt to litigate the merits of Plaintiffs’ infringement claim at this stage, resorting to matters outside the pleadings, without regard to controlling Federal Circuit precedent or a proper construction of the patent’s claim terms, is improper. And even if the merits are considered, Plaintiffs’ claims plainly survive at this stage.

Moreover, True Health’s inconsistent arguments show the weakness of its positions. On the one hand, True Health feigns surprise about the issuance of the ’242 patent and claims to need time to assess the claims, but then appears ready to address the merits of the new claims by going outside the pleadings and arguing at length that it allegedly does not infringe the ’242 patent. True Health has not, and cannot, overcome the liberal pleading standard—when leave to amend the pleadings is sought, district courts “should freely give leave when justice so requires.” Fed. R. Civ. P. 15(a)(2). Plaintiffs’ motion should be granted.

I. True Health Will Not Be Prejudiced By Plaintiffs’ Proposed Amendment

As Plaintiffs showed, True Health cannot possibly be prejudiced by granting Plaintiffs’ motion because *nothing has happened in this case yet*.¹ (Dkt. No. 23 at 7-8.) No Scheduling Order has issued yet, and discovery is not even open. Contrary to True Health’s false assertion

¹ Inexplicably, True Health asserts that it will allegedly be prejudiced unless all deadlines are adjusted. (Dkt. No. 30 at 10.) But the Scheduling Order has not yet issued, and there are no deadlines to adjust. True Health does not provide any basis for this Court to treat it differently from every other defendant on the Court’s docket.

that this amendment somehow deprives True Health of time it would otherwise be afforded (Dkt. No. 30 at 1), True Health faces no less time to defend against any new claims concerning the '242 patent than it does to defend against the existing claims concerning the two patents already in the case. True Health cannot be prejudiced by adding a new patent in a case where nothing has happened yet. *See Swimways Corp. v. Bravo Sports*, Case No. 2:08-cv-481, Dkt. No. 253 (E.D. Va. Sept. 8, 2009) (finding no prejudice and allowing amendment of the complaint to include a new patent after the case had been pending for almost a year).

In fact, Plaintiffs sought amendment within days of the patent issuing. The United States Patent and Trademark Office ("USPTO") issued the '242 patent on April 4, 2017. Before that patent issued, Plaintiffs had no rights to assert, and Plaintiffs had no control over when that patent might issue. Once it did issue, Plaintiffs engaged True Health in a face-to-face conversation about the new patent at the very next opportunity, on April 6, 2017. On April 10, 2017, when Defendant made clear that it opposed adding the '242 patent to the case, Plaintiffs immediately filed the instant motion seeking leave to amend the Complaint. Thus, Plaintiffs filed their request to amend within six days (including a weekend) of the patent issuing.

Moreover, the new allegations pertaining to the '242 patent involve largely the *same* infringing conduct and technology already at issue in this case. As a practical matter, litigating the '242 patent in this case makes sense. It not only serves judicial economy, but it also reduces the cost and time it would take for the parties to litigate the '242 patent in a separate action. Indeed, requiring Plaintiffs to litigate the '242 patent separately would prejudice both parties and burden the Court with another case on its docket.²

² Plaintiffs could have filed a new action asserting the '242 patent on April 4th and moved to consolidate it with this case. In that instance, the parties would be in essentially the same place, but this Court would have been unnecessarily burdened with opening a new case just to consolidate it with the current one.

Unable to address these unassailable facts, True Health contends that Plaintiffs should have either waited to bring this case until all of Plaintiffs' patents issued or raised the '242 patent before it issued. True Health's arguments are untenable.

First, waiting to bring the suit until all of the patents issued would have made no difference to True Health because no Scheduling Order has issued yet. However, waiting was potentially prejudicial to Plaintiffs. By filing suit on the day the first patent issued, Plaintiffs gave True Health notice of the patent, protected their ability to recover the full measure of damages to which they will be entitled, and provided True Health with an opportunity to cease its infringement and the accrual of damages. Indeed, in the previous Ohio Case, Plaintiffs sent a cease and desist letter instead of immediately suing True Health, but True Health ignored Plaintiffs' letter and instead cavalierly infringed Plaintiffs' patent rights. (Ohio Case Dkt. No. 7-10, attached as Exhibit 1.) Because Plaintiffs had every reason to expect that anything short of filing suit would meet with the same response, it was both appropriate and reasonable for Plaintiffs to sue immediately when the first patent issued.

Second, True Health makes much of the USPTO's notice on February 17, 2017, that the '242 patent would be allowed. Of course, this notice was a matter of public record. True Health and its own experienced patent counsel were surely aware of the related patent applications in the family at least by the time Plaintiffs' filed this lawsuit, if not before. But more to the point, until the '242 patent issued, Plaintiffs' rights remained inchoate. Plaintiffs have no control over when a patent will issue and, in fact, did not know until March 15, 2017, nearly a month after this case was filed and three weeks after the FAC was filed, that the '242 patent would issue on April 4, 2017. Moreover, until the patent actually issued, there was a chance that the USPTO

would delay issuing it.³ Courts have acknowledged that a patentee is not obligated to raise patent applications before they issue, even in circumstances where, unlike here, the failure to raise such application claims could actually be prejudicial. *See, e.g., Hynix Semiconductor Inc. v. Rambus, Inc.*, 609 F. Supp. 2d 988, 1024 (N.D. Cal. 2009) (finding patentee had not engaged in unfair competition when it did not disclose pending or anticipated patent applications to the standards organization because it had sound reasons for not disclosing them, including potential exposure to “various risks or claims”).

Because nothing has happened in the case, and because Plaintiffs did not delay in seeking to amend their Complaint with the '242 patent, there is no prejudice to True Health.

II. True Health’s Baseless Accusations Of Bad Faith Are Unfounded And Should Be Rejected

True Health spends pages casting aspersions on Plaintiffs’ motives, but True Health fails to offer any evidence or any applicable authority to support its false accusations. Indeed, the cases True Health cites show that to establish bad faith in this context, True Health must establish that Plaintiffs’ acted with intent to deceive, ulterior purposes, or abusively, and without a satisfactory explanation. (Dkt. No. 30 at 8-9.) Even “strategically delaying” to amend (which did not happen here) does not constitute bad faith “unless it is accompanied by prejudice to the other party.” *Bergano v. City of Virginia Beach*, No 2:15-cv-520, 2016 U.S. Dist. LEXIS 110664, at * _ (E.D. Va. Aug. 17, 2016). And there is no prejudice where the opposing party has “a fair opportunity to conduct necessary discovery on any issues introduced by the amendment,” which plainly is the case here where discovery has not even begun yet. *Id.*

³ In fact, just such a delay happened after the Notice of Allowance was issued for the first patent in this case, United States Patent No. 9,575,065. On December 30, 2016 the Notice of Allowance issued. The issue fee was paid on January 3, 2017, but the prosecution took a detour when it was remanded to the Examiner on January 4, 2017. *See* Transaction History from Public PAIR, attached as Exhibit 2.

True Health has not come close to meeting this standard. Plaintiffs' only motive is to enforce its patent rights as efficiently and expeditiously as possible to stop the continuing and irreparable harm Plaintiffs are suffering as a result of True Health's pervasive and unrepentant infringement. Plaintiffs' counsel has tried to be cooperative, but True Health has erected many unnecessary obstacles. Indeed, the real root of True Health's complaints is its counsel's discomfort with the Court's speed and its discontent with Plaintiffs' filing in this District, where a case schedule does not change once a Scheduling Order issues..

For example, at the outset of the case, apparently unaware of this Court's schedule for discovery, True Health requested a 90-day extension of time to answer the complaint. Plaintiffs pointed out that True Health's proposed extension was "roughly equivalent to [the] entire discovery period in this court." (Dkt. No. 23-3 at 3.) Plaintiffs then agreed to a reasonable 21-day extension, consistent with this Court's practices.⁴

Similarly, when Plaintiffs approached True Health with their proposed amendment to add the '242 patent to this case, Plaintiffs urged True Health to move quickly to reach an agreed-upon schedule for answering and briefing any motion on the pleadings because, under this Court's practice, the parties cannot adjust the schedule once the Scheduling Order issues. True Health objected to this procedure, demanding instead that Plaintiffs try to usurp this Court's authority and "guarantee that the Court will modify the entire schedule and trial date as if the

⁴ True Health criticizes Plaintiffs for raising the '242 patent after True Health filed its motion to dismiss and suggests that this somehow shows Plaintiffs "withheld its true position" for some "ulterior purpose." (Dkt. No. 30 at 9.) But True Health fails to tell the Court that when the parties discussed extending True Health's deadline to answer the FAC, Plaintiffs asked True Health if it was planning to answer the FAC or file some sort of motion on the pleadings. (Dkt. No. 23-3 at 3.) True Health declined to answer that question and indicated it thought the case should be stayed. (*Id.* at 2.) True Health never moved to stay this case, but instead filed a motion to dismiss on April 5, 2017. Once the patent issued, it was not unreasonable for Plaintiffs to wait one day to see how True Health responded to the FAC before making its final decision to assert the '242 patent in this case.

case first begins upon the filing of the newly amended complaint.” (Dkt. No. 23-4 at 2.) Again, because it appeared that True Health’s counsel was unaware of the impossibility of modifying the Court’s schedule, and in an effort to be accommodating, Plaintiffs’ counsel explained:

Thank you for getting back to us. We do not, however, agree that True Health will be prejudiced in any way by adding the ’242 patent now. The scheduling order has not yet issued, and when it does issue, the period for discovery will be the same whether there are two patents or three patents in the case. While we are willing to work with you to stipulate to a deadline for True Health to answer or renew its motion to dismiss, the other deadlines will be set by the Court, as you seem to recognize in your email. We do not agree that CCF/CHL should bring a separate suit to assert the ’242 patent. That patent just issued a few days ago, and nothing has happened in the case yet. Precedent in both the Fourth Circuit and the ED VA holds that leave to amend is routinely granted in these circumstances.

(*Id.*) Plaintiffs invited True Health to engage in further discussion, but given True Health’s demand for a “guarantee[d]” schedule and the trial date of its choosing (which Plaintiffs could not possibly do), Plaintiffs determined the parties were at an impasse. (*Id.*) Plaintiffs further gave True Health notice that it would be filing its motion later that day (April 10, 2017), and that it would be noticing the motion for hearing on Friday, April 21, 2017.⁵ True Health did not respond to Plaintiffs’ email. (*Id.*)

After Plaintiffs’ motion to amend was on file, counsel for Plaintiffs contacted True Health’s local counsel by telephone to further discuss the briefing and hearing schedule. Counsel for True Health did not return that call. Instead, on April 11, 2017, True Health sent an email complaining that it did not understand why Plaintiffs’ motion was noticed for hearing on April 21st:

⁵ Under this Court’s procedure for briefing and hearing nondispositive motions, Plaintiffs could have waited four days until 5:00 pm on Friday, April 14, 2017 to file their motion to amend and still noticed this motion for hearing on April 21, 2017. Plaintiffs instead filed as early as possible on Monday once they determined the parties had reached an impasse. This allowed True Health several extra days to brief the motion. True Health used the extra time to create a 162-page submission containing extensive amounts of factual material outside the pleadings, which is plainly improper when opposing a motion for leave to amend.

We see the Court set a hearing date for April 21 on your motion for leave. We don't believe you had a basis to notice an April 21 hearing date, and we intend to file a motion seeking to continue the hearing. Please let me know when you are available tomorrow to meet and confer. Please send me any authority you have supporting your request an "expedited procedure" where you noticed the hearing before our response would be due under the local rules.

(Exhibit 3 at 3.) Counsel for the parties conferred the next day. On that call, Plaintiffs' counsel explained this Court's schedule for briefing and hearing nondispositive motions, and the parties reached agreement on a briefing and hearing schedule for both Plaintiffs' motion to amend and True Health's pending motion to dismiss (if it is not mooted by resolution of this motion). (*Id.* at 1-3.)

Thus, contrary to True Health's unfounded assertions that Plaintiffs are somehow gaming the system, Plaintiffs have consistently tried to cooperate with True Health—within the confines of this Court's rules and without unnecessarily burdening the Court with unwarranted motion practice. True Health's discomfort with this Court's schedule does not amount to bad faith litigation conduct on Plaintiffs' part. *See Cellectis S.A. v. Precision Biosciences, Inc.*, 858 F. Supp. 2d 376, 385 (D. Del. 2012) (rejecting argument that Plaintiff sought leave to amend in bad faith and granting leave to amend).

True Health also seems to suggest that Plaintiffs acted in bad faith because they filed suit in Ohio on some of its earlier-issued patents, and then sought additional patent claims in the USPTO after some of its patents were invalidated. (Dkt. No. 30 at 4.) True Health's insinuations and accusations are unfounded. The patents at issue in Ohio were prosecuted before the Supreme Court issued its decisions clarifying the scope of patent-eligible subject matter under 35 U.S.C. § 101. Unfortunately, the district court in the Ohio Case determined (wrongly in Plaintiffs' view) that those patents were not valid under Section 101. That ruling is currently on appeal. True Health's assertion that the outcome of that appeal will somehow impact this

case is wrong. The patents on appeal are entirely different, were prosecuted without the benefit of the Supreme Court's guidance in *Mayo* and *Alice*,⁶ and were not examined by the USPTO under the current guidelines. In contrast, the patents in this case, as well as the '242 patent, were fully vetted by the USPTO in light of Section 101. The applicant overcame all of the examiner's rejections and concerns, and the examiner found the claims to be patent-eligible under the current guidelines. The fact that Plaintiffs returned to the USPTO to pursue additional patents after the district court in Ohio invalidated certain older patents shows only that Plaintiffs value these inventions and are willing to invest time and resources to obtain and protect their highly valuable patent rights. Thus, when some of the patents in the portfolio were invalidated, Plaintiffs properly sought new patents that were examined and issued under the current legal standards.

True Health cites two cases that purportedly support its claim of bad faith, but neither of them is applicable to this case. In *GSS Properties, Inc. v. Kendale Shopping Center, Inc.*, 119 F.R.D. 379 (M.D.N.C. 1988), the plaintiff-buyer of a shopping mall brought a claim for declaratory relief against the defendant-seller. After the suit was filed, the parties met to discuss settlement, but those talks were not fruitful. The plaintiff, obviously frustrated by the failure to settle the dispute, told the defendant he intended to retaliate by amending his claim to assert additional allegations of fraud based upon the same conduct alleged in the original complaint. In denying the motion to amend, the court noted that while the amendment was being made relatively early in the case, it was nonetheless brought in bad faith:

[T]he Court finds bad faith in plaintiff's withholding facts clearly known to it prior to the filing of the complaint and then moving to amend the complaint where the evidence suggests that plaintiff had an ulterior purpose of either attempting to force defendant to settle or punishing defendant for failing to settle.

⁶ *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012); *Alice Corp. Pty. Ltd. v. CLS Bank International*, 134 S. Ct. 2347 (2014).

Id. at 381. Unlike *GSS*, before April 4th Plaintiffs had no patent to assert. Once the patent issued and nothing of substance had happened in this case yet, Plaintiffs made a final decision to assert the '242 patent in this case. They then moved swiftly to add the '242 patent, and attempted to negotiate a schedule with True Health that conforms with this Court's schedule and allowed True Health sufficient time to answer. Plaintiffs did not withhold any information, nor did they seek to amend for some ulterior purpose. Quite simply, Plaintiffs seek this Court's assistance to stop True Health from infringing its patents.⁷

III. Defendant's Attempt To Litigate The Merits Of The Case And Resort To Matters Outside The Pleadings At This Stage Is Improper

True Health's second line of baseless attack on Plaintiffs' motion to amend is to argue, as all defendants do, that it does not infringe the patent at issue. However, litigating the substantive merits of the case, *i.e.*, assessing the merits of True Health's alleged non-infringement defense, at this stage of the case is entirely improper.

"Courts generally favor the 'resolution of cases on their merits.'" *Rambus, Inc. v. Infineon Techs., AG*, 304 F. Supp. 2d 812, 819 (E.D. Va. 2004) (quoting *Davis v. Piper Aircraft Corp.*, 615 F.2d 606, 613 (4th Cir. 1980)). "Thus, the substantive merits of a proposed claim are typically best left for later resolution, *e.g.*, under motions to dismiss or for summary judgment under Fed. R. Civ. P. 12(b)(6) or Fed. R. Civ. P. 56, respectively, or for resolution at trial." *Id.* "If the underlying facts or circumstances relied upon by a plaintiff may be a proper subject of relief, he ought to be afforded an opportunity to test his claim on the merits." *Foman v. Davis*, 371 U.S. 178, 182 (1962).

⁷ True Health's reliance on *Palacios v. U.S. Bank Nat'l Assoc.*, No. ELH-15-2081, 2016 WL 3440124 (D. Md. June 23, 2016) is even more misplaced. That case involved a *pro se* plaintiff that filed multiple lawsuits in several different fora naming a variety of banks, lawyers, and other defendants to stop foreclosure proceedings on his home. Plainly, that case is inapposite.

In this Circuit, a district court may deny a motion to amend on the ground of futility *only* “when the proposed amendment is “clearly insufficient on its face.” *Rambus*, 304 F. Supp. 2d at 819. “Just as when ruling on a Rule 12(b)(6) motion to dismiss, to determine the futility of amending a complaint, the Court must consider the motion without resolving factual disputes[.]” *Wilkins v. Wells Fargo Bank, N.A.*, No 2:15-cv-566, 2017 U.S. Dist. LEXIS 39105 (E.D. Va. Mar. 8, 2017). Indeed, “factual information and disputes regarding invalidity and non-infringement which go beyond the scope of the face of the proposed [amendment] ... are not appropriate for evaluating futility.” *ATI Indus. Automation v. Applied Robotics*, No. 1:09-CV-471, 2013 WL 6328487, at *2 (M.D.N.C. Dec. 4, 2013) (applying Fourth Circuit law). In *ATI*, the plaintiff asserted three patents against the defendant and the defendant sought to amend its answer and counterclaims to assert its own design patent. The plaintiff argued the amendment would be futile because the design patent was invalid. However, the court disagreed and allowed the amendment: “Plaintiff’s arguments involve factual information and disputes regarding invalidity and non-infringement which go beyond the scope of the face of the proposed counterclaim and thus are not appropriate for evaluating futility.” *Id.*

Similarly, in *Phoenix Solutions, Inc. v. Sony Elecs., Inc.*, 637 F. Supp. 2d 683, 692 (N.D. Cal. 2009), the court granted the motion to amend, explaining: “Intervoice improperly collapses the permissibility of amendment and the merits of Sony’s claim into one, when all that is required at this stage is to determine whether the proposed factual allegations would prejudice Intervoice in maintaining its defenses upon the merits.” *See also Transweb, LLC v. 3M Innovative Props. Co.*, No. 10-4413 (FSH), 2011 WL 2181189, at *9 (D.N.J. June 1, 2011) (granting motion to amend because “the question before the Court is not whether the movant will ultimately prevail, but rather whether the complaint set forth ‘enough facts to state a claim to

relief that is plausible on its face.”); *Artemi Ltd. v. Safe-Strap Co., Inc.*, 947 F. Supp. 2d 473, 478-479 (D.N.J. 2013) (declining to resolve issues requiring claim construction and a highly fact-specific inquiry on a motion to amend and granting motion).

Here, True Health goes well beyond the face of Plaintiffs’ proposed amendment, attacks the asserted facts, and challenges claim construction. But, as this case law demonstrates, that attack is improper in challenging a motion for leave to amend. Indeed, True Health introduces extraneous and voluminous material from outside the pleadings, including a Google screenshot, sample reports from nbwellness.com and cardiobrief.org, and a CHL Practioner’s Guide, just to name a few examples. (Dkt. No. 30 at 19.)

If True Health believes it has a legitimate non-infringement defense, it will have an opportunity to make those arguments once the ’242 patent is added to the case. But this is neither the time nor the place for the Court to resolve factual issues and decide the merits of True Health’s defense.

IV. True Health's Faulty Arguments On The Merits Are Based On Its Erroneous Interpretation Of The Claims And Ignores Controlling Federal Circuit Precedent

True Health’s non-infringement arguments should not even be considered on a motion for leave to amend, but in all events, its arguments are wrong because they are based on legally erroneous claim construction arguments that ignore controlling Federal Circuit law.

Claim 1 of the ’242 patent claims the following method:

1. A method for detecting MPO activity and/or mass and F2-isoprostane levels comprising:

a) providing:

i) a first assay for determining the level of MPO activity and/or MPO mass in a bodily sample from a human subject, wherein said first assay employs an anti-MPO antibody; and

ii) a second assay for determining a level of an MPO-generated oxidation product from said bodily sample, wherein said MPO-generated oxidation product comprises F2-isprostane (F2-iso); and

b) performing said first and second assays to obtain an MPO activity and/or mass level and an F2-isoprostane level from said bodily sample, wherein said bodily sample is selected from plasma, serum, urine, or blood.

(Exhibit 4 at C0000995.)

True Health's entire futility argument is based upon the legally erroneous premise that the claims of the '242 patent require that two tests claimed in the patented method be performed on a singular bodily sample, which True Health contends can only be a single sample of plasma, serum, urine or blood. (*See, e.g.*, Dkt. No. 30 at 14.)⁸ True Health is wrong.

The Federal Circuit has repeatedly explained that the default construction of "an indefinite article 'a' or 'an' in patent parlance carries the meaning of 'one or more' in open-ended claims containing the transitional phrase 'comprising.'" *Baldwin Graphic Sys., Inc. v. Siebert, Inc.* 512 F.3d 1338, 1342-43 (Fed. Cir. 2008) (quoting *KCJ Corp. v. Kinetic Concepts, Inc.*, 223 F.3d 1351, 1356 (Fed. Cir. 2000)). Indeed, the principle of claim construction "[t]hat 'a' or 'an' can mean 'one or more' is best described *as a rule*, rather than merely as a presumption or even a convention." *Baldwin*, 512 F.3d at 1342 (emphasis added). The exceptions to this rule are "extremely limited." *Id.* In fact, a patentee must evince a clear intent to limit "a" or "an" to "one." *Id.*

⁸ Before offering its current purported defense, True Health contended that it did not infringe the '242 patent because it "is a clinical laboratory and does not sell or provide testing kits, therefore, it does not perform the first step of claim 1 'providing: a first assay ... and a second assay ...'" (Dkt. No. 23-4 at 3.) True Health's strained construction of "providing" is untenable. Indeed, the Federal Circuit has construed "providing" in a method claim to mean "furnishing, supplying, making available, or preparing" and further held that anyone—the accused infringer or the end user of the infringer's products—can satisfy this providing step. *Meyer Intellectual Properties Ltd. v. Bodum, Inc.*, 690 F.3d 1354 (Fed. Cir. 2012). True Health has since abandoned this alleged defense in favor of the current, but similarly flawed, one-bodily-sample defense. Neither of True Health's alleged defenses has any merit.

Moreover, the subsequent use of definite articles “the” or “said” in a claim to refer back to the same claim term does *not* change the general plural rule, but simply reinvokes that non-singular meaning. *Id.* In fact, an exception to the general rule arises only when “the language of the claims themselves, the specification, or the prosecution history necessitate a departure from the rule.” *Id.* at 1343. For example, in *Baldwin*, the district court construed “a fabric roll” and “said fabric roll” to be limited to a singular roll. The Federal Circuit reversed, finding that “[t]his record does not contain a clear indication that the applicant departed from the general rule for the article ‘a.’ Nothing in the claim language, specification, or prosecution history compels an exceptional reading of ‘a’ in this case.” *Id.* at 1343.

Other cases similarly support Plaintiffs’ position that “a bodily sample” is not limited to a single sample of plasma, serum, urine or blood. For example, in *01 Communique Lab, Inc. v. Logmein, Inc.*, 687 F.3d 1292, 1297 (Fed. Cir. 2012), the Federal Circuit construed “a” locator server computer to mean “one or more” locator server computers. And, the Federal Circuit found that “nothing in the claim language or specification compel[led] a departure from the general rule [that ‘a’ and ‘an’ mean ‘one or more’].” *Id.* Further, “[e]ven if we were to conclude that the specification is ambiguous on this point, such ambiguity hardly is evidence of the clear intent necessary to overcome the effect of the general rule of claim construction applicable here.” *Id.*; *see also Stoneeagle Servs., Inc. v. Pay-Plus Solns., Inc.*, No. 8:13-cv-2240-T-33MAP, 2015 WL 3516410, at *9 (M.D. Fla. June 4, 2015) (declining to limit construction to a single file or document when the claim language and file history did not “clearly indicate[]” that “a singular meaning” was required).

The default construction of a/an/said bodily sample is further confirmed by the specification of the ’242 patent. In describing the invention, the patentee describes the invention

wherein MPO and F2-isoprostane are measured using different bodily samples. (See Exhibit 4 C0000982, Col. 4. Ln 19-26 (indicating that the MPO activity or mass or both can be determined by “said bodily sample being blood or a blood derivative” and levels of select MPO oxidation products are measured where “said bodily sample is blood, blood derivative, or urine”).)

True Health’s argument requires this Court to determine several factual issues as well as construction of the claims, both of which are inappropriate at this stage of the proceedings. To properly resolve the disputed issues requires factual development of the record and claim construction. Moreover, while True Health ignores the binding precedent from the Federal Circuit about the proper construction of a/an/said, it also misrepresents the file history as allegedly supporting its erroneous interpretation of the ’242 patent.

For example, True Health claims that “the patentees assert that ‘those of skill in the art would not have been easily led to determining the *levels of both markers ... in a bodily sample* which is selected from plasma, serum, urine, or blood.’” (Dkt. No. 30 at 16.) True Health ignores what the applicant actually said, and instead misleadingly attributes the statements *of the examiner* from another, related application to the applicant. (Exhibit 5 at C0000876.) applicants actually said: “[T]he combination of F2-isoprostane and MPO detection in plasma, serum, urine, or blood (as opposed to “any bodily sample”) would not be obvious in light of Daugherty et al. and Mehrabi et al.” (*Id.*)

True Health also quotes another portion of the file history, “there is no teaching or suggestion in the art to detect both MPO and F2-isoprostane levels in a plasma, serum, blood, or urine sample ...” (Dkt. No. 30 at 17), but leaves off the last part of the quote, “as the prior art previously cited by the Examiner (Daugherty et al. and Mehrabi et al.) are directed toward atherosclerotic lesions/vessels – not plasma, serum, blood, or urine.” (Exhibit 6 at C0000911.)

The full statements actually made by the applicants are important to show the context for the statements and a proper interpretation of it. Indeed, when applicant's full statements are considered, it is clear that the distinction being made is between a sample that comprises bodily fluids and the lesion samples taught in the prior art.

Moreover, the language True Health quotes does not limit the sample to a single sample of plasma, serum, urine or blood, but naturally read could be a sample collected that includes both blood and urine. When bodily fluids are taken for diagnostic purposes at the essentially same time, whether multiple vials of blood are drawn or a single vial of blood and a container of urine, they are often referred to collectively as "a bodily sample." The distinction between multiple blood draws or a blood draw plus urine sample is neither medically nor legally significant.

Indeed, True Health's overly restrictive construction makes no sense because under its reading, one would not infringe the claims if the MPO test was performed on one vial of blood and the F2-isoprostane test was performed on a second vial of blood drawn from the same patient at essentially the same time.

But in all events, this motion is not the place to resolve disputed claim constructions, or consider the merits of True Health's defenses. Plainly, there will be claim construction and other issues that the Court will have to resolve in the course of this patent infringement case, but the existence of such disputes and True Health's contention that it has defenses to Plaintiffs' infringement claims are irrelevant to the matter at hand. Plaintiffs seek leave to add the '242 patent to the case, the case is in its infancy, and there is no harm or prejudice to True Health if the motion is granted. As the rules admonish, this Court "should freely give leave when justice so requires." Thus, this Court should grant Plaintiffs' motion for leave to amend.

V. A Single Motion On The Pleadings Is More Efficient

Finally, True Health claims that it would be unfairly prejudiced if its motion to dismiss were superseded and without prejudice to refiling it fourteen days after entry of the SAC. (Dkt. No. 30 at 20.) Plaintiffs suggested this procedure to minimize the burden on the Court and to avoid multiple motions on the pleadings. As with Plaintiffs' other good faith attempts to litigate this case in an orderly fashion, True Health tries to twist Plaintiffs' position into something untoward. (*Id.*) The parties have worked out a briefing and hearing schedule on the currently pending motion to dismiss. If the Court prefers to address the motions separately, Plaintiffs will abide by that schedule. But if the Court would prefer to address all grounds for motions brought on the pleadings in a single motion, Plaintiffs suggest that the pending motion to dismiss be denied as moot without prejudice to True Health's refiling it in due course.

VI. Conclusion

For all these reasons, Plaintiffs respectfully request that this Court grant their motion for leave to file the Amended Complaint, and order True Health to answer, move or otherwise plead in response by no later than fourteen (14) days after entry of the Amended Complaint. Further, if the Court grants the motion, Plaintiffs' request that the Court deny True Health's motion to dismiss as moot as it will be superseded by the Amended Complaint, but without prejudice to True Health's renewing motion when it answers the new Complaint.

Dated: April 20, 2017

Respectfully submitted,

/s/ Tara Lynn R. Zurawski

Tara Lynn R. Zurawski (VA Bar No. 73602)

Lawrence D. Rosenberg (*pro hac vice*)

JONES DAY

51 Louisiana Avenue, N.W.

Washington, DC 20001.2113

Telephone: (202) 879-3939

Facsimile: (202) 626-1700

Email: tzurawski@jonesday.com

Email: ldrosenberg@jonesday.com

David M. Maiorana (VA Bar No. 42334)

Calvin P. Griffith (*pro hac vice*)

Susan M. Gerber (*pro hac vice*)

JONES DAY

North Point, 901 Lakeside Avenue

Cleveland, OH 44114

Telephone: (216) 586-3939

Facsimile: (216) 579-0212

Email: dmaiorana@jonesday.com

Email: cpgriffith@jonesday.com

Email: smgerber@jonesday.com

Counsel for Plaintiffs

The Cleveland Clinic Foundation and

Cleveland HeartLab, Inc.

CERTIFICATE OF SERVICE

I certify that on April 20, 2017, a copy of the foregoing was filed electronically with the Clerk of Court using the ECF system. A copy of this filing will be served on Defendant by operation of the Court's ECF system.

Dated: April 20, 2017

/s/ Tara Lynn R. Zurawski

Tara Lynn R. Zurawski (VA Bar No. 73602)

Counsel for Plaintiffs

*The Cleveland Clinic Foundation and Cleveland
HeartLab, Inc.*